REMARKS

Claims 134-157 were pending in the subject application. Applicants have cancelled all previously pending claims without disclaimer or prejudice as to Applicants' right to pursue the subject matter of these claims in the future, and present new claims 158-202.

The subject application is a continuation of U.S. Serial No. 10/346,853, filed January 17, 2003, which is a continuation of U.S. Serial No. 09/100,812, filed June 19, 1998, now U.S. Patent No. 6,573,099 B2, issued June 3, 2003, which claims priority of Australian Provisional Patent Application No. PP2492, filed March 20, 1998 (the "Priority Application"). New claims 158-202 are fully supported by each application as follows:

Claim	Element	Support
158	"double-stranded DNA construct"	page 1, lines 7-8 "synthetic genes and genetic constructs," Examples 1-8
173	"An animal cell having a double-stranded DNA"	page 1, lines 5-7 "synthetic genes for modifying endogenous gene expression in a cell, tissue or organ of a transgenic organism, in particular a transgenic animal or plant,"
188	"process for delaying, repressing or otherwise reducing the expression of a target gene in an animal cell"	page 1, lines 7-9 "synthetic genes and genetic constructs which are capable of repressing delaying or otherwise reducing the expression of an endogenous gene or a target gene in an organism when introduced thereto"
158, 173, 188	"first structural gene sequence"	page 3, lines 11-14 "wherein said synthetic gene at least comprises multiple structural gene sequences, wherein each of said structural gene sequences comprises a nucleotide sequence which is substantially identical to the nucleotide sequence of said target gene"

Claim	Element	Support
158, 173, 188	"identical to the nucleotide sequence of a region of a target gene in an animal cell"	Page 16, lines 12-16 "synthetic gene which is capable of modifying the expression of a target gene in a cell, tissue or organ, wherein said synthetic gene at least comprises multiple structural gene sequences wherein each of said structural gene sequences comprises a nucleotide sequence which is substantially identical to the nucleotide sequence of the target gene"
158, 173, 188	"second structural gene sequence identical in sequence to, and in an inverted orientation relative to, the first structural gene sequence"	page 18, lines 16-20 "preferably, the multiple structural gene unit comprises two structural genes in a head-to-tail or head-to-head configuration. More preferably, the multiple structural gene unit comprises two identical or substantially identical structural genes or a homologue, analogue or derivative thereof in a head-to-tail configuration as a direct repeat or alternatively, in a head-to-head configuration as an inverted repeat or palindrome.
158, 173, 188	"a stuffer fragment which consists of nucleotides and which separates and links the first and second structural gene sequences"	page 19, lines 14-19 "the individual structural genes comprising the multiple structural gene unit may be further spatially separated by the addition of a linker molecule or 'stuffer fragment' there between."
158, 173, 188	"a promoter operable in the animal cell"	page 3, lines 15-16 "single promoter sequence which is operable in said cell, tissue or organ"
158, 173, 188	"a transcription termination sequence active in the animal cell"	page 22, lines 12-13 "the synthetic genes described supra may further comprise one or more transcription termination sequences"
158, 173, 188	"wherein the first structural gene sequence, the stuffer fragment and the second structural gene sequence are all operably connected to the promoter and the transcription termination sequence"	page 14, lines 6-9 "terms 'in operable connection with' or 'operably under the control' or similar shall be taken to indicate that expression of the structural gene is under the control of the promoter sequence with which it is spatially connected; in a cell, tissue, organ or whole organism"
159, 174, 189	"the target gene is endogenous to the animal cell"	page 7, lines 18-20 "Preferred target genes include, but are not limited to ... genes which are endogenous to the cell, tissue or organ"

Claim	Element	Support
160, 175, 190	"region of the target gene is in an exon"	page 6, lines 22-23 "mRNA or cDNA corresponding to the coding regions (i.e. exons) optionally comprising 5'· or 3'-untranslated sequences linked thereto"
161, 176, 191	"target gene is a foreign gene to the animal cell"	page 7, lines 18-20 "preferred target genes include, but are not limited to ... foreign genes which have been introduced into the cel], tissue or organ"
162, 177, 192	"target gene is a viral gene"	page 7, lines 18-19 "preferred target genes include, but are not limited to viral genes"
163, 178, 193	"viral gene encodes a DNA polymerase, a RNA polymerase, or a viral coat protein"	page 7, lines 22-24 "wherein the target is a viral gene, it is particularly preferred that the viral gene encodes a function which is essential for replication or reproduction of the virus, such as but not limited to a DNA polymerase or RNA polymerase gene or a viral coat protein gene"
164, 179, 194	"viral gene is from a lentivirus"	page 7, lines 25-27 "the target gene comprises an RNA polymerase gene derived from ... a lentivirus"
165, 180, 195	"viral gene is from an immunodeficiency virus"	page 7, lines 25-28 "the target gene comprises an RNA polymerase gene derived from ... an immunodeficiency virus (eg. HIV-1)"
166, 181, 196	"viral gene is from a single-stranded (+) RNA virus"	page 7, lines 25-26 "the target gene comprises an RNA polymerase gene derived from a single-stranded (+) RNA virus"
167, 182, 197	"viral gene is from a double-stranded DNA virus"	page 7, lines 25-29 "target gene comprises ... a DNA polymerase derived from a double-stranded DNA virus"
168, 183, 198	"target gene is a transgene"	page 8, lines 6-7 "preferred foreign target genes include any transgene which has been introduced to the cell, tissue or organ"
169, 184, 199	"stuffer fragment is a sequence of nucleotides 10-50 nucleotides in length"	page 19, lines 24-26 "the stuffer fragment comprises a sequence of nucleotides of at least about 10 to 50 nucleotides in length"
170, 185, 200	"stuffer fragment is a sequence of nucleotides 50-100 nucleotides in length"	"the stuffer fragment comprises a sequence of nucleotides of ... at least about 50-100 nucleotides in length "

Claim	Element	Support
171, 186, 201	"the stuffer fragment is a sequence of nucleotides 100-500 nucleotides in length"	"the stuffer fragment comprises a sequence of nucleotides of ... at least about 100-500 nucleotides in length"
172, 187, 202	"a third structural gene sequence whose nucleotide sequence is identical to the nucleotide sequence of a different region of the same target gene or a different target gene in the animal cell, and a fourth structural gene sequence identical in sequence to, and in an inverted orientation relative thereto"	page 17, lines 4-5 "preferably, the multiple structural gene comprises at least 2-4 individual structural gene sequences;" page 17, lines 24-26 "each structural gene contained within the multiple structural gene unit of the subject synthetic gene may comprise a nucleotide sequence which is substantially identical to a different target gene in the same organism"

Upon entry of this Amendment, claims 158-202 will be pending in the subject application.

Claims Rejected Under 35 U.S.C. §112, first paragraph

On page 2 of the March 9, 2010 Final Office Action, the Examiner rejected claims 134, 135, and 142-154, and 221-224 under 35 U.S.C. §112, as allegedly failing to comply with the written description requirement. The Examiner's specific rationale is set forth on pages 2-6 of the March 9, 2010 Final Office Action.

In response, Applicants note that cancellation of the rejected claims renders this rejection moot.

Claims Rejected Under 35 U.S.C. §103(a)

On page 7 of the March 9, 2010 Final Office Action, the Examiner rejected claims 134-147 and 150-155 under 35 U.S.C. §103, as allegedly obvious over Fire et al. (U.S. Patent No. 6,506,559) in view of Agrawal et al. (WO 94/01550), Gold et al. (U.S. Patent No. 5,270,163) Kotin et al. (U.S. Patent No. 5,580,703) and Chatterjee et al. (5,474,935). The Examiner's specific rationale

is set forth on pages 7-19 of the March 9, 2010 Final Office Action.

In response, Applicants note that cancellation of the rejected claims renders this rejection moot. Applicants maintain that new claims 158-202 are patentable over the prior art of record.